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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,880	01/15/2002	Jean-Claude Bystryn	392/25799-DB/RDK	5017

7590 07/27/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,880	BYSTRYN, JEAN-CLAUDE	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Bystryn J-C

Election/Restrictions

1. Applicant's election with traverse of group I (claims 1-2, and 4) in the reply filed on 4/25/2005 is acknowledged. The traversal is on the ground(s) that the inventions should not be separated because there is no burden of search. Specifically, applicant argues that claims drawn to a composition and a method of using the composition are "intimately intertwined" despite the different classification of the claimed inventions. In addition, applicant also contend that they were in possession issued patents which claims inventions that are both products and methods of use and therefore the instant invention should not be separated. This is not found persuasive because the instantly claimed inventions are drawn to two distinct and patentably different inventions. For example, the search for the product claim does not require a search for the method of using that product, because the searches are conducted in different databases. With regard to the arguments concerning prior patented applications, the examiner is not familiar with the prosecution history and therefore cannot comment on the issues surrounding those cases.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-9 are pending, claims 3, 5-9 are withdrawn from further consideration as being drawn to a non-elected invention.
3. Claims 1-2 and 4 are examined on the merits.

Specification

4. The priority data in the first line of the specification needs to be updated to reflect the current status of US application 08/865,112 now US Patent 6,338,853.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-2, and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Bystryn J.C *et al* (J. Biol. Resp. Mod. 1986; 5(3):211-224). The claims of the instant invention are drawn to either a polyvalent vaccine composition or a vaccine composition comprising multiple melanoma-associated cell surface antigens shed from multiple different human melanoma cell lines in serum free media.

7. Bystryn *et al* teach a composition comprising shed melanoma cell surface antigen derived from 4 melanoma cell lines that were cultured in serum free media. Moreover, Bystryn *et al* teach that a “broad range of different melanoma antigens” are present. The claimed composition appears to be the same as that taught in the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the

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claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Therefore, the claims are anticipated by Bumol *et al.*

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albino *et al* (J. Exp Med. 1981; 154:1764-1778) in view of Gupta *et al* (J. Natl. Cancer Inst. 1984 Jan; 72(1): 67-74).

a. Albino *et al* teach the characterization of multiple melanoma associated surface antigens derived from multiple different cell lines (see page 1770 Table 1, and page 1775, for example).

b. Albino *et al* does not specifically teach the culturing of the multiple different melanoma cell lines in a serum free media.

c. Gupta *et al* teach the purification of melanoma-associated surface antigens from "spent" media, wherein the media is serum free media.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to manufacture a polyvalent melanoma vaccine comprising

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multiple melanoma associated surface antigens derived from multiple cell lines cultured in serum free media. One of ordinary skill in the art would have been motivated to do so because the Albino *et al* taught that melanoma cell lines produce a diversity of surface antigens (see page 1770); Gupta *et al* taught that melanoma surface antigens are released from the surface of the melanoma cell and that these antigens could be purified in media free of serum proteins (see page 67, for example). One of skill in the art would therefore find motivation to combine the references because the use of serum-free media provided for a means to isolate relatively purified population of melanoma-associated surface antigens without contamination with serum proteins found in the culturing media containing serum (i.e. fetal bovine serum). Moreover, the use of multiple melanoma cell lines, as taught by Albino *et al*, provides for a diversity of melanoma antigens for which to generate a more diverse immune response. One of skill in the art would find a reasonable expectation of success in doing so because Gupta *et al* taught that the purification of melanoma surface antigen from serum free media would provided for an enriched population of surface antigen that was immunogenic.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-2 and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,030,621; claim 1-2 and 4 of U.S. Patent No. 5,635,188; claim 1-2,4, and 10-11 of U.S. Patent No. 5,993,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention encompass the same scope as that taught in all of the cited US Patents.

Therefore, a polyvalent vaccine comprising multiple melanoma associated cell surface antigens would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have been motivated because all of the cited issued patents teach what appears to be the same polyvalent multiple melanoma associated cell surface antigen vaccine. Although the

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method steps appear to slightly different, the means or process of producing a product does impart onto a product a patentable distinct limitation, because the inventions are drawn to the product, per se. Thus it would appear that there are no structurally distinguishing features between the issued patents and the instantly claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

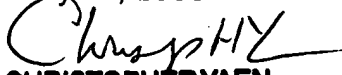
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

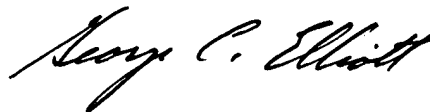
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen

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July 22, 2005


CHRISTOPHER YAEN
PATENT EXAMINER



DIRECTOR

TECHNOLOGY CENTER 1600